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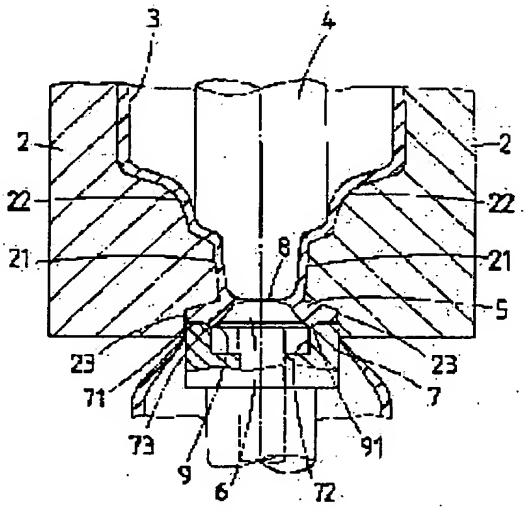
(54) THIN FILM INTEGRATED MOUTH PART OF SYNTHETIC RESIN CONTAINER FOR AQUEOUS INFUSION AND MOLDING OF MOUTH PART IN THIN FILM

(57)Abstract:
PROBLEM TO BE SOLVED: To reduce the number of parts and eliminate the possibilities of liquid leak due to imperfect welding by blocking the mouth part of a synthetic resin container for an aqueous infusion by blow molding and at the same time, forming a thin film on the blocked part.
SOLUTION: A parison 3 is inserted into the halves 2, 2 of a split molding die and is thermally softened. Next, a blow nozzle 4 is introduced into the neck part 21 of the molding die 2, and the thermally molten parison 3 is welded from the neck part 21 to a shoulder part 22. Further, the parison 3 is extruded through a nozzle 4 and an overhang part 5 of synthetic resin which overhangs onto the inner face of the parison 3 is formed in the mouth parts 23, 23 of the molding die 2. In addition, a force plunger 7 for molding the mouth part and a force plunger 6 for molding a thin film are inserted into the mouth part 23, and the remaining clearance of the force plungers 6, 7 in the mouth part 23 is filled with the overhang part 5 to form a thin film 8 between the force plunger 6 and the tip of the nozzle 4. After that, an annular recessed part 9 is formed with the surrounding part of the force plunger 6 and a plate-like depression 73, and a molten synthetic resin is packed into this recessed part 9 to mold an annular protrusion 91.



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CLAIMS

[Claim(s)]
[Claim 1] Thin film unification regio oralis of the container made of synthetic resin for infusion solutions characterized by fabricating a thin film in the lock out section by blow molding while blockading the regio oralis of the container made of synthetic resin for infusion solutions.
[Claim 2] Thin film unification regio oralis of the container made of synthetic resin according to claim 1 for infusion solutions characterized by having fabricated the thin film in the lock out section, and preparing an annular height in the periphery of a thin film.
[Claim 3] Insert the fused tube-like parison in the flash mold for blow molding, and a blowing-in nozzle is inserted in the neck section of these metal mold. The melting synthetic resin of the neck section is made to jut out in the bore direction of tube-like parison as the synthetic-resin overhang section by the regio oralis of the flash mold for blow molding. The force plunger for regio-oralis shaping which protruded the force plunger for thin film shaping free [extrusion] is inserted in the regio oralis of the flash mold for blow molding. The regio-oralis thin film shaping approach of the container made of synthetic resin for infusion solutions characterized by having extruded this force plunger for thin film shaping to the regio oralis of the flash mold for blow molding, and fabricating a thin film with a blowing-in nozzle and the force plunger for thin film shaping.
[Claim 4] The regio-oralis thin film shaping approach of the container made of synthetic resin according to claim 3 for infusion solutions characterized by having fabricated the depression to the force-plunger side for regio-oralis shaping, having fabricated the annular crevice between this depression and the perimeter section of the force plunger for thin film shaping, and fabricating an annular height to the periphery of a thin film.

[Translation done.]

DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] While this invention blockades the regio oralis of the container made of synthetic resin for infusion solutions by blow molding, it relates to the thin film unification regio oralis of the container made of synthetic resin for infusion solutions and the regio-oralis thin film shaping approach which unified and fabricated the thin film in the lock out section.
[0002]
[Description of the Prior Art] Generally, the drugs with which the container made of synthetic resin for infusion solutions was filled up must be sealed by the aseptic condition with a strict contents drug solution from a viewpoint of health nature and safety to just before use. Therefore, for example, the rubber stopper and the stopper made of synthetic resin are usually used together in the completeness of liquid-spill prevention like JP,3-28944,B and JP,7-29336,B by the regio oralis which especially a liquid spill tends to produce at the term ** sake.
[0003] In this JP,3-28944,B, the stopper made of synthetic resin for holding the sealing performance of a container and the rubber stopper for liquid-spill prevention are laid on top of the regio oralis of the container made of synthetic resin for infusion solutions in the shape of sequential insertion. And by carrying out the heating press of the regio-oralis upper part and the stopper upper part made of synthetic resin using a ****** heater etc., the curve unification of these upper parts is carried out at the inner sense, and fixed support of said rubber stopper is carried out. In this case, the center section of the stopper made of synthetic resin is thin so that a coring phenomenon may not arise, and is fabricated in the shape of a thin film so that it may be easy to penetrate a hypodermic needle etc.
[0004] Moreover, the approach of fabricating the film of an infusion solution plug ultra-thin is indicated by JP,7-29336,B.
[0005] Furthermore, the top lid separately fabricated to the bottom lid (equivalent to said stopper made of synthetic resin) which arranged the film for obturation is fitted in an upper limit opening edge through a rubber stopper on this film for obturation, it acts as both ** arrival with ultrasonic heating etc., and what carries out shaping unification is indicated by JP,3-94234,U.
[0006] Moreover, in each official report of JP,4-22745,Y, JP,3-49262,B, and JP,5-72830,B, powder pharmaceutical preparation, lyophilized products, etc. are held in containers, such as a vial, as drugs of a dissolution mold at the time of the use for securing the stability of drugs etc. And it connects using the connecting means of the double ended needle which formed successively the needles which are mutually open for free passage up and down just before using containers, such as this vial, and the container which held solutions, such as water for injection and a physiological salt solution, or a connection tube, and the kit container which dissolves drugs with a solution is proposed.
[0007] Furthermore, the fluid channel section and the stopper member which were intercepted with the thin film by the stopper member which has a penetration means in each official report of JP,5-72830,B and JP,7-40425,A at the time of the use for preventing mixing of a solution and drugs till use, respectively are indicated.
[0008] In this JP,5-72830,B, a capsule is connected with the flexible container which has the

fluid channel section closed by upper limit by the obturator membrane, and the drugs container by which the regio oralis was sealed with the plug in which **** is possible is held in said capsule. Moreover, as a free passage means to open the interior of said flexible container and a drugs container for free passage, it has a hub in the middle and the reusable puncture needle of the hollow which has the edge of a blade is needed for both ends. And after the plug of a drugs container is run through with one cutting edge of the reusable puncture needle, the infusion solution container which needs the control means which controls free passage sequence so that the obturator membrane of a flexible container is run through with the cutting edge of another side of a reusable puncture needle is indicated.

[0009] Moreover, the solution container of a kit container has the viewpoint of the ease of abandonment processing, safety, and economical efficiency to a desirable product made of synthetic resin, and in order to use it especially with a closed system, it is desirable [a container] to consider as the container made of elasticity synthetic resin manufactured by the bag container made of synthetic resin or blow molding. So, in JP,6-61845,B, in order to attach the stopper member which equipped the bag or the elasticity container with the penetration means at the time of use of a thin film etc., the stopper member by which the thin film for the closures penetrated by the puncture member to the film web material of two sheets or inflation tube material at the time of use was fabricated is fitted in. Then, the tubular film process which carries out ** arrival with a heat seal or a RF seal is indicated. Moreover, in JP,5-92479,A, in order to attach said stopper member, the approach of equipping with a stopper member and carrying out blow molding to the sheet-like parison of two sheets or tubular parison is indicated.

[0010] On the other hand, in blow molding, JP,7-68627,A is made to carry out press deformation with the rod which established the parison edge of parison in the Ayr blowing nozzle free [actuation], and the approach of casting a thin film at said parison edge is indicated.

[0011]

[Problem(s) to be Solved by the Invention] Like each official report of JP,3-28944,B, JP,7-29336,B, and JP,3-94234,U, the rubber stopper and the stopper made of synthetic resin are used together in the completeness of liquid-spill prevention by the regio oralis which especially a liquid spill tends to produce at the term ** sake. Therefore, there are many component part mark of a container, manufacture of an infusion solution container takes time and effort, a manufacturing installation also becomes complicated, and there is a trouble of being attached to cost quantity. Moreover, these stopper members etc. have the danger of being easy to generate poor ** arrival, in the case of ** arrival.

[0012] Moreover, with the kit container which dissolves drugs at the time of use in order to secure the stability of drugs etc., the solution with which the solution container was filled up was transported using the double ended needle, the connection tube, etc. into the container which held drugs, and the mixed dissolution is carried out. However, this mixed dissolution activity is complicated and requires time and effort, and a double ended needle, a connection tube, etc. have the trouble that drugs and a solution are easy to be polluted with saprophytic bacteria in order to contact the open air.

[0013] Therefore, the kit container of JP,4-22745,Y which held the double ended needle in the cap-like rubber stopper upper part attached in the thin neck regio oralis of the body of a solution container in the protective cap beforehand is proposed. Moreover, kit containers which intervened reusable puncture needles, such as a double ended needle, and have arranged beforehand containers, such as a vial which held the drugs of a dissolution mold at the time of use, and the flexible container filled up with the solution up and down, such as JP,3-49262,B and JP,5-72830,B, are also proposed.

[0014] In the kit container of each official report of these JP,4-22745,Y, JP,3-49262,B, and JP,5-72830,B, in order to require the stopper member which possesses a penetration means at the time of use of a thin film etc., there are many component part mark of a container and there is said same trouble.

[0015] Moreover, it is necessary to fit in or insert the stopper member by which the thin film for the closures penetrated by the puncture member was fabricated, and in JP,6-61845,B and JP,5-92479,A each official report, there are many component part mark of a container at the time of

use, and said same trouble is in it.
[0016] In JP,7-68627,A, since the thin film for regio-oralis lock out is really fabricated with shaping, the danger of poor ** arrival is avoided, but since the rod which can operate freely inside the Ayr blowing nozzle is prepared, the configuration of the Ayr blowing nozzle is complicated. Moreover, since the path of the Ayr blowing nozzle becomes large, shaping of a container with the small aperture of the regio oralis has the trouble that it cannot do.
[0017] This invention aims at offering the regio oralis of the container made of synthetic resin for infusion solutions and the regio-oralis thin film shaping approach which a thin film is fabricated to lock out and coincidence of the regio oralis, there are few components mark, there is no **** of the liquid spill by poor ** arrival, and **** of permeation of the saprophytic bacteria by carrying in of a stopper member does not have separately, either by blow molding.
[0018] Moreover, this invention does not need to prepare the rod which can operate freely inside a blowing-in nozzle, can make the path of a blowing-in nozzle thin, and aims at offering the regio oralis of the container made of synthetic resin for infusion solutions suitable for shaping of a container with the small aperture of the regio oralis, and the regio-oralis thin film shaping approach.
[0019]
[Means for Solving the Problem] In order to have been made in view of the above trouble and to solve this technical problem, this invention fabricated the thin film in the lock out section by blow molding as regio oralis of the container made of synthetic resin for infusion solutions while blockading the regio oralis of the container made of synthetic resin for infusion solutions.
[0020] Moreover, as regio oralis of another container made of synthetic resin for infusion solutions, while fabricating the thin film in the lock out section, the annular height was prepared in the periphery of a thin film.
[0021] The fused tube-like parison is inserted in the flash mold for blow molding as the regio-oralis thin film shaping approach of the container made of synthetic resin for infusion solutions, and a blowing-in nozzle is inserted in the neck section of these metal mold.
[0022] And the melting synthetic resin of the neck section is made to jut out in the bore direction of tube-like parison as the synthetic-resin overhang section by the regio oralis of the flash mold for blow molding.
[0023] Moreover, the force plunger for regio-oralis shaping which protruded the force plunger for thin film shaping free [extrusion] is inserted in the regio oralis of the flash mold for blow molding.
[0024] Next, this force plunger for thin film shaping was extruded to the regio oralis of the flash mold for blow molding, and the thin film was fabricated with the blowing-in nozzle and the force plunger for thin film shaping.
[0025] Moreover, as the regio-oralis thin film shaping approach of another container made of synthetic resin for infusion solutions, the depression was fabricated to the force-plunger side for regio-oralis shaping, the annular crevice was fabricated between this depression and the perimeter section of the force plunger for thin film shaping, and the annular height was fabricated to the periphery of a thin film.
[0026]
[Embodiment of the Invention] It explains to a detail based on the accompanying drawing which showed an example of the operation gestalt about the thin film unification regio oralis of the container made of synthetic resin of this invention for infusion solutions, and the regio-oralis thin film shaping approach below.
[0027] Drawing 1 shows the front view of the container made of synthetic resin of this invention for infusion solutions, drawing 2 shows this bottom view, drawing 3 is this side elevation and drawing 4 shows the A-A line sectional view of drawing 1 . Drawing 5 - drawing 8 show the regio-oralis thin film shaping approach of the container made of synthetic resin of this invention for infusion solutions.
[0028] For example, with an extrusion method, the tube-like parison 3 is inserted into the flash mold 2 for blow molding of the container 1 made of synthetic resin for infusion solutions, and 2, is heated, and the thermoplastic synthetic resin by which heating melting was carried out is

changed into the condition of softening.
[0029] Next, while blowing in into the neck sections 21 and 21 of the flash molds 2 and 2 for blow molding, inserting a nozzle 4 and sticking the parison 3 which carried out heating fusion to shoulders 22 and 22 from the neck sections 21 and 21 of flash molds 2 and 2, parison 3 is extruded by said nozzle 4.
[0030] The synthetic-resin overhang section 5 which jutted out the synthetic resin which constitutes this stuck tube-like parison 3 to parison 3 inside within the regio oralis 23 of flash molds 2 and 2 and 23 by extruding with a nozzle 4 is formed.
[0031] Furthermore, the crevice 72 which inserts the reverse dished (it is **** repetition ****** about a pan) force plunger 6 for thin film shaping in apical surface 71 center section fitted in the regio oralis 23 and 23 of flash molds 2 and 2 is fabricated, and the force plunger 7 for regio-oralis shaping which inserted this force plunger 6 free [extrusion] from the apical surface 71 is formed.
[0032] Moreover, when the force plunger 6 for thin film shaping is inserted in said crevice 72, it is made for the apical surface 71 of the force plunger 7 for regio-oralis shaping and the tip of the force plunger 6 for thin film shaping to become flat-tapped, and they fabricate the dished depression 73 of a major diameter from a crevice 72 a little to an apical surface 71.
[0033] And the force plunger 6 for thin film shaping is inserted into the regio oralis 23 and 23 at the same time it fits in the regio oralis 23 and 23 of flash molds 2 and 2 the force plunger 7 for regio-oralis shaping which inserted the force plunger 6 for thin film shaping in the crevice 72 and inserts the force plunger 6 for thin film shaping in regio oralis 23 and 23, as shown in drawing 7 .
[0034] If the force plunger 7 for regio-oralis shaping and the force plunger 6 for thin film shaping are inserted into the regio oralis 23 and 23, as shown in drawing 8 , the remaining gaps of the regio oralis 23 and the force plungers 6 and 7 in 23 will be filled with said synthetic-resin overhang section 5, it will blow in as a force plunger 6, and a thin film 8 will be fabricated at the tip with a nozzle 4.
[0035] Moreover, the annular height 91 is fabricated by fabricating the annular crevice 9 in the dished depression 73 fabricated to the perimeter section and the apical surface 71 of said force plunger 6 projected from the crevice 72 in the apical surface 71 of this force plunger 7, and filling up this crevice 9 with melting synthetic resin.
[0036] After fabricating the regio oralis equipped with the thin film, a blowing-in nozzle retreats, instead, a drug solution restoration nozzle (not shown) is inserted into the container made of synthetic resin for infusion solutions, and it is filled up with a drug solution, and it seals by carrying out ****** arrival of the insertion regio oralis to after an appropriate time with metal mold etc., the regio oralis 10 is fabricated, and it considers as the container 1 made of synthetic resin for infusion solutions. under the present circumstances, the time of use -- opening -- it is desirable to prepare the thin-walled part for fracture in the regio oralis 10 of the direction which is not equipped with the thin film so that easily.
[0037] Or using the approach which changed to preparing the thin-walled part for fracture, for example, was indicated by JP,7-137160,A by this applicant, regio-oralis molding afterbaking of the regio oralis 10 of the direction which is not equipped with the thin film of the container 1 made of synthetic resin for infusion solutions is carried out, and it carries out pressurization insertion of the rubber stopper 11 for liquid spill prevention again at the time of use. This presses the synthetic-resin overhang section produced in the container regio-oralis 10 upper part using a force plunger, it is made to curve to the method of inside, a synthetic-resin overhang section tip is inserted in the annular crevice of the rubber stopper top-face periphery section, and it is good also as rubber stopper insertion regio oralis (drawing 9).
[0038] At the time of use, the regio oralis equipped with the thin film carries out the puncture of the drilling members, such as a double ended needle, and a spike, a hypodermic needle, and uses them as instillation etc. Or ****** arrival of the penetration equipment 12 is further carried out at the time of the use which built in drug solution circulation members, such as a double ended needle, and it is good also as a kit product (drawing 10).
[0039] As a kit product, penetration equipment 12 is connected with the container 1 made of synthetic resin for infusion solutions at the time of the use which built in drug solution

circulation members, such as a double ended needle. By operating a drug solution circulation member and tearing a thin film, after carrying out the puncture of the vial in which the solid preparations of a dissolution mold were held through drug solution circulation members, such as a double ended needle of the hollow prepared in penetration equipment 12 at the time of use, at the time of use The solution in the container 1 made of synthetic resin for infusion solutions and the solid preparations in a vial are mixed, and what obtains a desired drug solution is mentioned (drawing 10).

[0040] Or the capsule which has the vial in which the solid preparations of a dissolution mold were held at the time of use is connected with the container 1 made of synthetic resin for infusion solutions through a liquid path, and what mixes the solution in the container 1 made of synthetic resin for infusion solutions and the solid preparations in a capsule is mentioned by operating drug solution circulation members, such as a double ended needle of the hollow prepared in the capsule, and tearing a thin film (not shown).

[0041]

[Effect of the Invention] Since the container made of synthetic resin for infusion solutions manufactured by the regio-oralis thin film shaping approach of this invention really fabricated the thin film for the contents liquid closures on the body of a container, it becomes unnecessary to prepare a stopper member separately, and there are few container components mark, and a routing is also simplified. Moreover, there is also no danger of the liquid spill by poor ** arrival.

[0042] Furthermore, since there is also no need for use of a stopper member separately, permeation of the saprophytic bacteria by carrying in of a stopper member can be prevented.

[0043] Since the annular height projected up was prepared in the periphery around a thin film and this annular height plays a role of the guide section at the time of the puncture of drilling members, such as a double ended needle, and a spike, a hypodermic needle, the regio oralis equipped with the thin film manufactured by this invention can carry out the puncture of this drilling member easily and quickly, and does not drill other parts accidentally.

[0044] Moreover, this annular height is effective also as a positioning means at the time of attaching penetration equipment at the time of the use which built drug solution circulation members, such as a double ended needle, in the regio oralis equipped with the thin film.

[0045] Furthermore, since the regio oralis equipped with the thin film manufactured by this invention fabricates a thin film by the press by the blowing-in nozzle and the force plunger for thin film shaping, it can process the configuration of the thin film section circumference free by changing the configuration of the press side of a blowing-in nozzle and the force plunger for thin film shaping.

[Translation done.]

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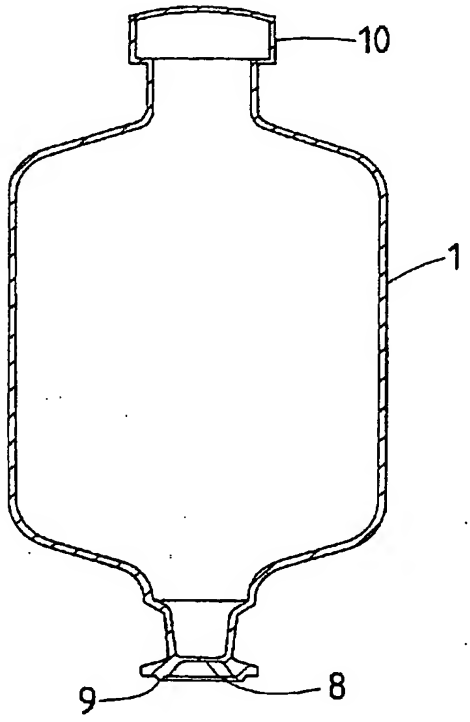
(54)【発明の名称】輸液用合成樹脂製容器の薄膜一体化口部および口部薄膜成形方法

(57)【要約】

【課題】　口径の小さな輸液容器の製造を可能とし、部品点数が少なく、熔着不良による液漏れの惧れがなく、雑菌の浸入の惧れをなくす。

【解決手段】　輸液用合成樹脂製容器１の口部として、ブロー成形により、輸液用合成樹脂製容器の口部を閉塞すると共に、閉塞部に薄膜８を成形し、薄膜の周辺部に環状突起部９１を設けた。



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【特許請求の範囲】

【請求項１】　ブロー成形により、輸液用合成樹脂製容器の口部を閉塞すると共に、閉塞部に薄膜を成形したことを特徴とする輸液用合成樹脂製容器の薄膜一体化口部。

【請求項２】　閉塞部に薄膜を成形し、薄膜の周辺部に環状突起部を設けたことを特徴とする請求項１記載の輸液用合成樹脂製容器の薄膜一体化口部。

【請求項３】　熔融したチューブ状パリソンをブロー成形用合せ金型に挿入し、吹込みノズルをこれら金型のネック部に差込み、ネック部の熔融合成樹脂をブロー成形用合せ金型の口部でチューブ状パリソンの内径方向に合成樹脂張出し部として張り出させ、薄膜成形用押型を押出し自在に突設した口部成形用押型をブロー成形用合せ金型の口部に挿入し、この薄膜成形用押型をブロー成形用合せ金型の口部に押出し、吹込みノズルと薄膜成形用押型で薄膜を成形したことを特徴とする輸液用合成樹脂製容器の口部薄膜成形方法。

【請求項４】　口部成形用押型面に凹みを成形し、この凹みと薄膜成形用押型の周囲部との間に環状凹部を成形し、薄膜の周辺部に環状突起部を成形したことを特徴とする請求項３記載の輸液用合成樹脂製容器の口部薄膜成形方法。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】本発明は、ブロー成形により輸液用合成樹脂製容器の口部を閉塞すると同時に閉塞部に薄膜を一体化して成形した輸液用合成樹脂製容器の薄膜一体化口部および口部薄膜成形方法に関する。

【０００２】

【従来の技術】一般に、輸液用合成樹脂製容器に充填された医薬品は、衛生性および安全性の観点から使用直前まで内容薬液が厳密な無菌状態で密封されていなければならない。そのため、例えば、特公平３－２８９４４号公報、特公平７－２９３３６号公報のように、特に液漏れが生じやすい口部には、液漏れ防止の完全を期すために、通常ゴム栓と合成樹脂製の口栓が併用されている。

【０００３】この特公平３－２８９４４号公報では、輸液用合成樹脂製容器の口部に、容器の密封性を保持するための合成樹脂製口栓および液漏れ防止用ゴム栓とを順次嵌入状に重ね合せている。そして、口部上部と合成樹脂製口栓上部とを熔着用ヒーター等を用いて加熱押圧することにより、これら上部を内向きに湾曲一体化し、前記ゴム栓を固定支持している。この場合、合成樹脂製口栓の中央部は、注射針等が貫通し易いように、またコアリング現象が生じないように薄く、薄膜状に成形されている。

【０００４】また、特公平７－２９３３６号公報には、輸液栓体の膜を極薄に成形する方法が開示されている。

【０００５】さらに、実開平３－９４２３４号公報には、上端開口縁部に封口用フィルムを配した下側蓋体（前記合成樹脂製口栓に相当）に、別途成形した上側蓋体をこの封口用フィルム上にゴム栓を介して挿嵌し、超音波加熱等により両者を熔着して成形一体化するものが開示されている。

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【０００６】また、実公平４－２２７４５号、特公平３－４９２６２号、特公平５－７２８３０号の各公報では、医薬品の安定性等を確保するための使用時溶解型の薬剤として粉末製剤や凍結乾燥製剤等をバイアル等の容器に収容する。そして、このバイアル等の容器と注射用水や生理食塩液等の溶解液を収容した容器とを使用直前に、上下に相互に連通する針を連設した両頭針あるいは連結チューブ等の接続手段を用いて接続して、薬剤を溶解液で溶解するキット容器が提案されている。

【０００７】さらに、特公平５－７２８３０号、特開平７－４０４２５号の各公報には、それぞれ使用時まで溶解液と薬剤の混合を防ぐための使用時貫通手段を有する口栓部材に、薄膜により遮断された流体通路部や口栓部材が開示されている。

【０００８】この特公平５－７２８３０号公報では、上端に閉鎖膜で閉鎖された流体通路部を有する可撓性容器にカプセルを連結し、口部が刺通可能な栓で密封された薬剤容器を前記カプセル内に保持する。また、前記可撓性容器の内部と薬剤容器の内部とを連通する連通手段として、中間にハブを有し両端に刃先を有する中空の穿刺針を必要とする。そして、その穿刺針の一方の刃によって薬剤容器の栓が刺通された後、穿刺針の他方の刃によって可撓性容器の閉鎖膜が刺通されるように連通順序を制御する制御手段を必要とする輸液容器が開示されている。

【０００９】また、キット容器の溶解液容器は、廃棄処理の容易性、安全性、経済性の観点から、合成樹脂製が好ましく、特にクローズド・システムで使用するためには、合成樹脂製バッグ容器若しくはブロー成形により製造された軟質合成樹脂製容器とするのが好ましい。そこで、特公平６－６１８４５号公報等では、バッグ若しくは軟質容器に薄膜等の使用時貫通手段を備えた口栓部材を取付けるために、２枚のフィルムシート材またはインフレーションチューブ材に使用時に穿刺部材で貫通される封止用薄膜が成形された口栓部材を挿嵌する。その後、熱シールまたは高周波シールで熔着するインフレーション法が開示されている。また、特開平５－９２４７９号公報等では、前記口栓部材を取付けるために、２枚のシート状パリソンまたは管状パリソンに口栓部材を装着し、ブロー成形する方法が開示されている。

【００１０】他方、特開平７－６８６２７号公報には、ブロー成形において、パリソンのパリソン端部をエアー吹込ノズルに作動自在に設けた棒体で押圧変形させ、前記パリソン端部に薄膜を成型する方法が開示されている。

【００１１】
【発明が解決しようとする課題】特公平３－２８９４４号、特公平７－２９３３６号、実開平３－９４２３４号の各公報のように、特に液漏れが生じやすい口部には、液漏れ防止の完全を期すためにゴム栓と合成樹脂製の口栓が併用されている。そのため、容器の構成部品点数が多く、輸液容器の製造に手間がかかり、製造装置も複雑になり、コスト高に付くという問題点がある。また、これらの口栓部材等は、熔着の際に熔着不良が発生し易いという危険性がある。
【００１２】また、医薬品の安定性等を確保するために薬剤を使用時に溶解するキット容器では、薬剤を収容した容器内に溶解液容器に充填された溶解液を両頭針や連結チューブ等を使って移送し、混合溶解している。しかし、この混合溶解作業は煩雑で手間がかかり、また、両頭針や連結チューブ等は外気と接触するため、薬剤や溶解液が雑菌で汚染され易いといった問題点がある。
【００１３】そのため、溶解液容器本体の細頸口部に嵌着したキャップ状ゴム栓上方に両頭針を予め保護キャップ内に収容した実公平４－２２７４５号公報のキット容器が提案されている。また、使用時溶解型の薬剤を収容したバイアル等の容器と溶解液を充填した可撓性容器を両頭針等の穿刺針を介在して予め上下に配置した特公平３－４９２６２号公報、特公平５－７２８３０号公報等のキット容器も提案されている。
【００１４】これら実公平４－２２７４５号、特公平３－４９２６２号、特公平５－７２８３０号の各公報のキット容器においては、薄膜等の使用時貫通手段を具備した口栓部材を要するため、容器の構成部品点数が多く、前記同様の問題点がある。
【００１５】また、特公平６－６１８４５号、特開平５－９２４７９号各公報では、使用時に穿刺部材により貫通される封止用薄膜が成形された口栓部材を挿嵌または挿着する必要があり、容器の構成部品点数が多く、前記同様の問題点がある。
【００１６】特開平７－６８６２７号公報では、一体成形により口部閉塞のための薄膜を成形するので、熔着不良の危険性は回避されているが、エアー吹込ノズルの内部に作動自在な棒体が設けられているから、エアー吹込ノズルの構成が複雑化する。また、エアー吹込ノズルの径が大きくなるため、口部の口径の小さな容器の成形はできないという問題点がある。
【００１７】本発明は、ブロー成形により、口部の閉塞と同時に薄膜を成形し、部品点数が少なく、熔着不良による液漏れの惧れがなく、別途口栓部材の搬入による雑菌の浸入の惧れもない輸液用合成樹脂製容器の口部と口部薄膜成形方法を提供することを目的とする。
【００１８】また、本発明は、吹込みノズルの内部に作動自在な棒体を設ける必要がなく、吹込みノズルの径を細くすることができ、口部の口径の小さな容器の成形に適した輸液用合成樹脂製容器の口部と口部薄膜成形方法を提供することを目的とする。
【００１９】
【課題を解決するための手段】本発明は、以上の問題点に鑑みてなされたもので、この課題を解決するために、輸液用合成樹脂製容器の口部として、ブロー成形により、輸液用合成樹脂製容器の口部を閉塞すると共に、閉塞部に薄膜を成形した。
【００２０】また、別の輸液用合成樹脂製容器の口部として、閉塞部に薄膜を成形すると共に、薄膜の周辺部に環状突起部を設けた。
【００２１】輸液用合成樹脂製容器の口部薄膜成形方法として、熔融したチューブ状パリソンをブロー成形用合せ金型に挿入し、吹込みノズルをこれら金型のネック部に差込む。
【００２２】そして、ネック部の熔融合成樹脂をブロー成形用合せ金型の口部でチューブ状パリソンの内径方向に合成樹脂張出し部として張り出させる。
【００２３】また、薄膜成形用押型を押出し自在に突設した口部成形用押型をブロー成形用合せ金型の口部に挿入する。
【００２４】次に、この薄膜成形用押型をブロー成形用合せ金型の口部に押出し、吹込みノズルと薄膜成形用押型で薄膜を成形した。
【００２５】また、別の輸液用合成樹脂製容器の口部薄膜成形方法として、口部成形用押型面に凹みを成形し、この凹みと薄膜成形用押型の周囲部との間に環状凹部を成形し、薄膜の周辺部に環状突起部を成形した。
【００２６】
【発明の実施の形態】以下に本発明の輸液用合成樹脂製容器の薄膜一体化口部および口部薄膜成形方法に関する実施形態の一例を示した添付図面に基づいて詳細に説明する。
【００２７】図１は本発明の輸液用合成樹脂製容器の正面図を示し、図２は同底面図を示し、図３は同側面図で、図４は図１のＡ－Ａ線断面図を示すものである。図５～図８は本発明の輸液用合成樹脂製容器の口部薄膜成形方法を示したものである。
【００２８】加熱熔融された熱可塑性合成樹脂を例えば押出し方式によって、チューブ状のパリソン３を輸液用合成樹脂製容器１のブロー成形用合せ金型２，２内に挿入し、加熱して軟化の状態にする。
【００２９】次に、ブロー成形用合せ金型２，２のネック部２１，２１に吹込みノズル４を挿入し、加熱熔融したパリソン３を合せ金型２，２のネック部２１，２１から肩部２２，２２に密着させると共に、パリソン３を前記ノズル４により押し出す。
【００３０】この密着したチューブ状パリソン３を構成する合成樹脂を、ノズル４で押し出すことにより、合せ金型２，２の口部２３，２３内で、パリソン３内面へ張

出した合成樹脂張出し部５を設ける。

【００３１】さらに、合せ金型２，２の口部２３，２３に挿嵌する、先端面７１中央部に逆皿状（皿をひっくり返した状態）の薄膜成形用押型６を嵌入する凹部７２を成形し、先端面７１よりこの押型６を押出し自在に挿着した口部成形用押型７を設ける。

【００３２】また、前記凹部７２に薄膜成形用押型６を嵌入した際に、口部成形用押型７の先端面７１と薄膜成形用押型６の先端とが面一になるようにし、先端面７１に凹部７２よりやや大径の皿状凹み７３を成形する。

【００３３】そして、図７に示すように、凹部７２に薄膜成形用押型６を嵌入した口部成形用押型７を合せ金型２，２の口部２３，２３に挿嵌し、薄膜成形用押型６を口部２３，２３に挿入すると同時に、薄膜成形用押型６を口部２３，２３内に挿入する。

【００３４】口部２３，２３内に口部成形用押型７と薄膜成形用押型６とを挿入すると、図８に示すように、前記合成樹脂張出し部５で口部２３，２３内における押型６、７の残りの間隙を充たし、押型６と吹込みノズル４との先端で薄膜８を成形する。

【００３５】また、この押型７の先端面７１における凹部７２より突出した前記押型６の周囲部と先端面７１に成形した皿状凹み７３で環状凹部９を成形し、熔融合成樹脂をこの凹部９に充填することにより、環状突起部９１を成形する。

【００３６】薄膜を備えた口部を成形した後、吹込みノズルが退却し、代わって薬液充填ノズル（図示せず）を輸液用合成樹脂製容器内に挿入して薬液を充填し、しかる後に挿入口部を例えば金型等により加熱熔着することにより密封して口部１０を成形し、輸液用合成樹脂製容器１とする。この際、使用時に開封容易なように、薄膜を備えていない方の口部１０に破断のための薄肉部を設けておくのが好ましい。

【００３７】あるいはまた、輸液用合成樹脂製容器１の薄膜を備えていない方の口部１０は、破断のための薄肉部を設けておくことに替えて、例えば、本件出願人による特開平７－１３７１６０号公報に記載された方法を用いて、口部成型後加熱し、使用時漏液防止用ゴム栓１１を加圧挿入する。それにより、容器口部１０上部に生じた合成樹脂張出し部を押型を用いて押圧して内方へ湾曲させ、合成樹脂張出し部先端をゴム栓上面外周部の環状凹部に挿入して、ゴム栓嵌入口部としてもよい（図９）。

【００３８】薄膜を備えた口部は、使用時に両頭針やスパイク、注射針等の穿通部材を穿刺し、点滴液等として使用する。あるいはさらに、両頭針等の薬液流通部材を内蔵した使用時貫通装置１２を加熱熔着し、キット製品としてもよい（図１０）。

【００３９】キット製品としては、両頭針等の薬液流通部材を内蔵した使用時貫通装置１２が輸液用合成樹脂製容器１と接続され、使用時貫通装置１２内に設けられた中空の両頭針等の薬液流通部材を介して使用時溶解型の固形製剤が収容されたバイアルを穿刺した後、薬液流通部材を作動させて薄膜を破ることによって、輸液用合成樹脂製容器１内の溶解液とバイアル内の固形製剤を混合させ、所望の薬液を得るものなどが挙げられる（図１０）。

【００４０】あるいは、使用時溶解型の固形製剤が収容されたバイアルを有するカプセルが液体通路を介して輸液用合成樹脂製容器１と接続され、カプセル内に設けられた中空の両頭針等の薬液流通部材を作動させて薄膜を破ることによって、輸液用合成樹脂製容器１内の溶解液とカプセル内の固形製剤を混合させるものが挙げられる（図示せず）。

【００４１】

【発明の効果】本発明の口部薄膜成形方法により製造される輸液用合成樹脂製容器は、容器本体に内容液封止用薄膜を一体成形したから、別途口栓部材を用意する必要がなくなり、容器部品点数が少なく、作業工程も簡素化される。また、熔着不良による液漏れの危険性もない。

【００４２】さらに、別途口栓部材の使用の必要もないから、口栓部材の搬入による雑菌の浸入を防ぐことができる。

【００４３】本発明により製造された薄膜を備えた口部は、薄膜の周囲の周辺部に上方に突出した環状突起部を設けたので、この環状突起部が両頭針やスパイク、注射針等の穿通部材の穿刺時にガイド部としての役割を果たすため、かかる穿通部材を容易に、かつ素早く穿刺でき、また、誤って他の部位を穿通してしまうこともない。

【００４４】また、この環状突起部は、薄膜を備えた口部に両頭針等の薬液流通部材を内蔵した使用時貫通装置を取り付ける際の位置決め手段としても有効である。

【００４５】さらに、本発明により製造された薄膜を備えた口部は、吹込みノズルと薄膜成形用押型による押圧によって薄膜を成形するから、吹込みノズルおよび薄膜成形用押型の押圧面の形状を変更することによって、薄膜部周辺の形状を自在に加工することができる。

【図面の簡単な説明】

【図１】本発明の輸液用合成樹脂製容器の正面図である。

【図２】本発明の輸液用合成樹脂製容器の底面図である。

【図３】本発明の輸液用合成樹脂製容器の側面図である。

【図４】図２のＡ－Ａ線断面図である。

【図５】本発明の輸液用合成樹脂製容器の口部薄膜成形方法を示したもので、パリソンをブロー成形用合せ金型に挿入時のものである。

【図６】本発明の輸液用合成樹脂製容器の口部薄膜成形

方法を示したもので、吹込みノズルをブロー成形用合せ金型のネック部に挿入時のものである。

【図７】本発明の輸液用合成樹脂製容器の口部薄膜成形方法を示したもので、口部成形用押型をブロー成形用合せ金型の口部に挿入直後のものである。

【図８】本発明の輸液用合成樹脂製容器の口部薄膜成形方法を示したもので、口部成形用押型と薄膜成形用押型とをブロー成形用合せ金型の口部に挿入時のものである。

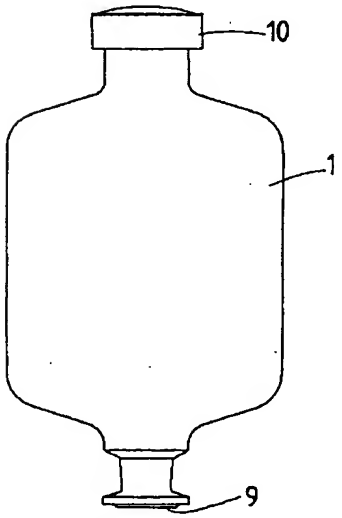
【図９】本発明の輸液用合成樹脂製容器の薄膜を備えていない方の口部に使用時漏液防止用ゴム栓を加圧挿入したものの図４と同様のＡ－Ａ線断面図である。

【図１０】本発明の輸液用合成樹脂製容器の薄膜を備えていない方の口部に使用時漏液防止用ゴム栓を加圧挿入し、さらに薄膜を備えた口部に薬液流通部材を内蔵した使用時貫通装置を取り付けたものの正面図である。

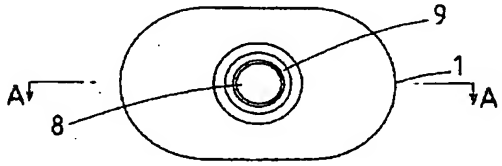
【符号の説明】

１　輸液用合成樹脂製容器
２　ブロー成形用金型
２１　ネック部
２２　肩部
２３　口部
３　パリソン
４　吹込みノズル
５　合成樹脂張出し部
６　薄膜成形用押型
７　口部成形用押型
７１　先端面
７２　凹部
７３　皿状凹み
８　薄膜
９　環状凹部
９１　環状突起部
１０　口部
１１　ゴム栓
１２　使用時貫通装置

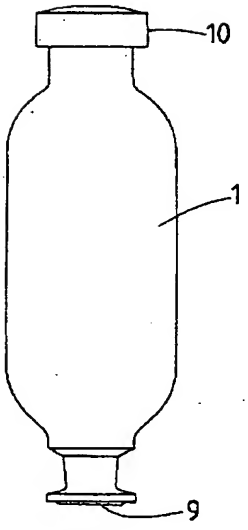
【図１】



【図２】



【図３】



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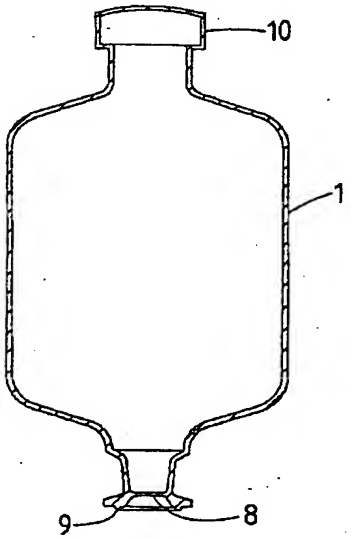

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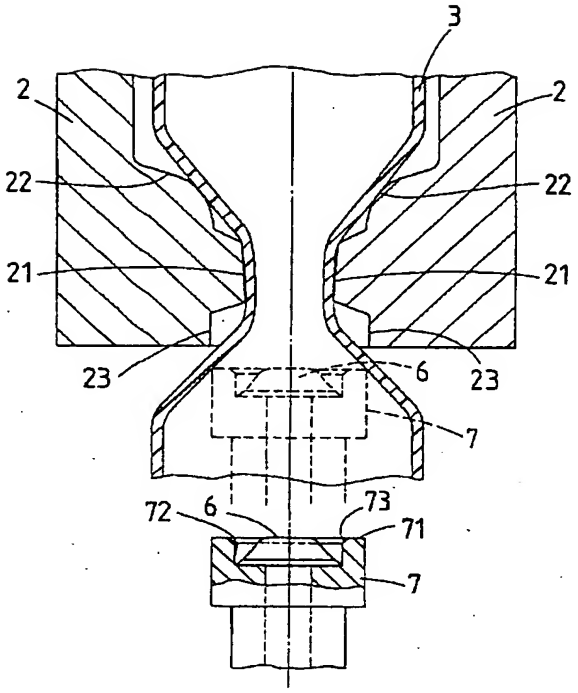
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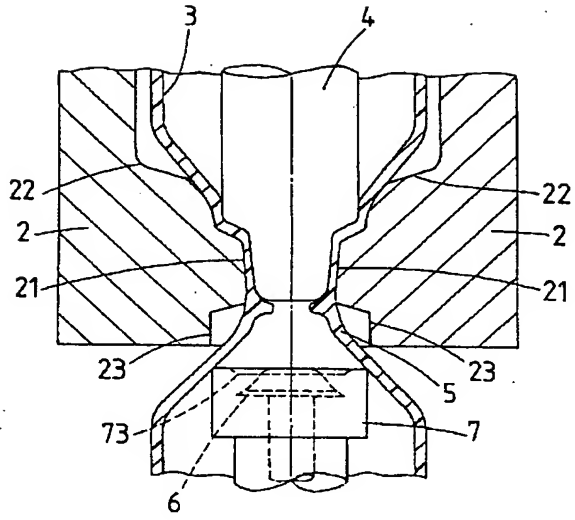
【図６】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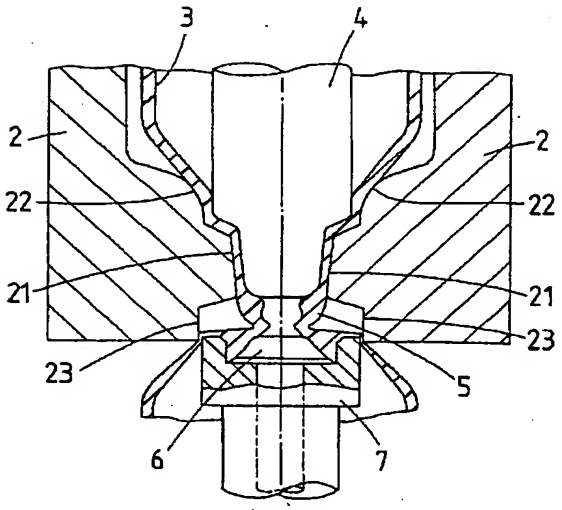
【図７】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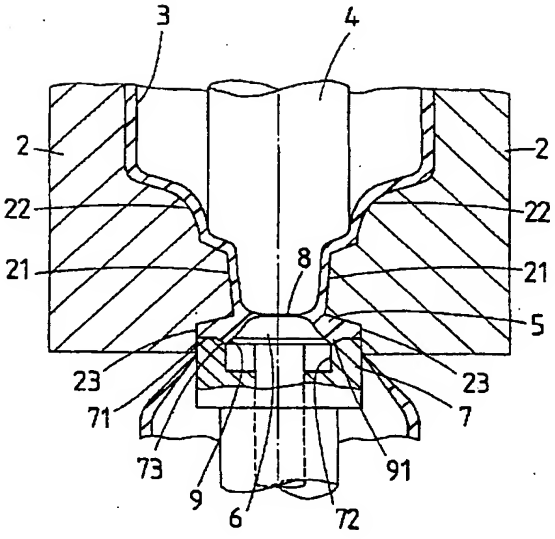
【図８】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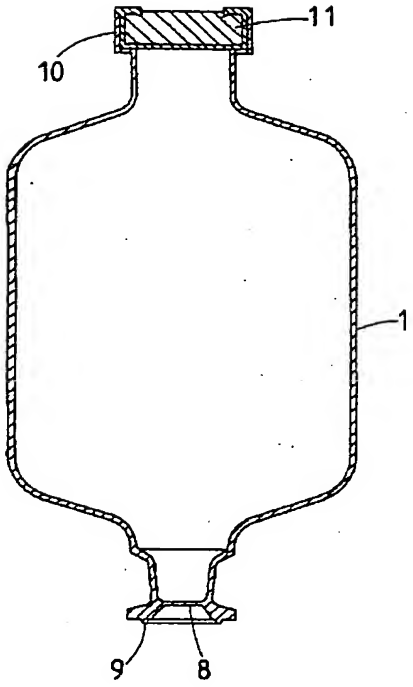
【図９】



【図１０】